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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,677	03/26/2004	Michel Schneider	1201-99	7873
23117	7590	11/28/2006		
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER SCHLIENTZ, LEAH H	
			ART UNIT	PAPER NUMBER

1618

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/809,677

Applicant(s)

SCHNEIDER ET AL.

Examiner

Leah Schlientz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/26/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/26/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

DETAILED ACTION

Priority

The instant application is a continuation of a continuation-in-part of four separate chains of applications. Some of the genera or sub-genera now claimed are not found in all of the applications to which this application claims priority. The effective priority date of any given claim is the date at which Applicant first conveyed the inventive concept of the claim as a whole. Set forth below are the apparent effective filing dates for the genera now claimed.

1) The first disclosure of the term Freon was in EP90810262, filed April 2, 1990; therefore, the inventive concept of using any Freon as a gas was first conveyed in said application.

2) The first disclosure of the term "halogenated hydrocarbon" was in EP92810046, filed January 23, 1992; therefore, the inventive concept of the using any halogenated hydrocarbon as a gas was first conveyed in said application.

3) The first disclosure of the genus embraced by the term "fluorinated compounds" is in US 09/266,889, filed March 12, 1999; therefore the inventive concept of using any fluorinated gas was first conveyed in said application.

4) The first disclosure of stabilizing the microbubbles with a surfactant was in EP90810262, filed April 2, 1990, therefore, the inventive concept of using a surfactant was first conveyed in said application.

In accordance with the effective priority dates set forth above, it appears that the pending claim includes a genus which has an effective priority date which is no earlier than the filing date of the '889 application, filed March 12, 1999.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

There are numerous patents/applications that may necessitate a double patenting rejection due to the breadth of the claim, as can be seen by an inventor's name search of US patents and applications. It would constitute an undue burden for the examiner to specifically analyze each of these numerous patents and/or applications. A quick search turned up the patents and pending applications below that appear to have similar subject matter as claimed. The examiner requests a complete

list of both patents and pending applications which may initiate a double patenting rejection because of the undue burden presented by the numerous overlapping subject matter with the instant claims.

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,271,928, 5,380,519, 5,413,774, 5,445,813, 5,518,991, 5,531,980, 5,556,610, 5,578,292, 5,597,414, 5,643,297, 5,643,553, 5,658,551, 5,633,601, 5,686,060, 5,711,933, 5,846,518, 5,863,520, 6,136,293, 6,139,818, 6,183,725, 6,484,494, 6,585,955, 6,592,846, 6,613,306, 6,881,397, 6,989,141, and 7,033,574.

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/102,684, 10/129,390, 10/336760, 10/336823, 10/355,052, 10/385,473, 10/544123, 10/78185, 10/831,165, 11/202,008, 11/085,169, 11/231,865, 11/444,362, etc. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim is generic to the claims of the various patents. For example, the patented claims are drawn to specific methods of ultrasound imaging using specific compositions (e.g. having specific gases and/or shell materials, etc.). The compositions recited in these patented method claims are directly within the scope of the instant claim. This is a genus-species situation, wherein the numerous species of the patented claims are directly within the scope of the large genus of the

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pending claims, thereby creating an "anticipation situation" in obvious-type double patenting.

Specification

The disclosure is objected to because of the following informalities: the disclosure does not contain a brief description of the drawings. See MPEP § 608.01(f). A reference to and brief description of the drawing(s) is necessary as set forth in 37 CFR 1.74. Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b,e) as being anticipated by any one of Klaveness (US 5,558,856), Unger (US 5,776,429), Unger (5,585,112), Quay (5,558,094), or Quay (5,393,524).

The instant claim is drawn to microbubbles comprising a fluorinated gas (in its broadest limitation) which is stabilized by a surfactant.

Klaveness, Unger '429, Unger '112, Quay '094, or Quay '524 each teach suspensions of microbubbles which contain various surfactants including lipids and further teach a number of fluorinated gases. Klaveness teaches the combination of a

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lipid (i.e. surfactant) with a polysaccharide as well as a fluorine containing gas (examples 19-22). Unger '429 and Unger '112 teach surfactant stabilized microspheres which contain a fluorinated gas (examples 1,6, and 7 or examples 1, 3, 4, 5, and 10, respectively). Quay ('524, column 7, lines 59 – column 8 line 50; Table II) or Quay ('094, example 1, column 16, lines 53 – column 17, line 7) teaches microbubbles stabilized with other materials than lipids, as well as generally teaching a variety of shell material. Quay and Quay teach several fluorinated gases as well as a specific example containing a fluorinated gas and a surfactant. Therefore, Klaveness, Unger '429, Unger '112, Quay '094, or Quay '524 fully anticipate the instant claim.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lohrmann (US 5,716,597).

Lohrmann teaches compositions comprising fluorinated gases with surfactants (columns 3 – 4 and examples 4, 7, and 10), their preparation, and their use in ultrasonic imaging.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Unger (US 5,088,499), Ryan (US 4,900,540) or Ryan (US 4,544,545) in view of Ticker (US 4,265,251).

Unger discloses ultrasound contrast agents comprising liposomes (e.g. microbubbles) stabilized by a surfactant i.e. phospholipids at the gas/liquid interface (see abstract and column 9, lines 9+). The microbubbles may encapsulate various gases, e.g. nitrogen, etc. (see column 13, line 2).

Ryan '540 discloses ultrasound contrast agents comprising liposomes having a phospholipid surfactant that encapsulates a gas (see abstract). The liposomes encapsulate various gases (see column 2, lines 52+).

Ryan '545 discloses contrast agents comprising liposomes in lamellar form that are made of various phospholipids surfactants (see column 2, lines 40+). The liposomes may encapsulate various materials, including perfluorohydrocarbons (e.g. which would encompass Freons) and other gases for use in ultrasound imaging (see column 3).

Unger, Ryan '540 and '545 fail to disclose the use of a "Freon" gas.

Tickner discloses contrast agent comprising gas microballoons and teaches that "Freon" may be used in an equivalent manner to other known gases, see column 6, line 66.

It would have been obvious to one of ordinary skill in the art to include a Freon in the microballoons disclosed by Unger, Ryan '540 or Ryan '545 because it is known in the art that Freon may be used in an equivalent manner to other known gases for microbubble contrast agents, as shown by Tickner. One of ordinary skill in the art would have been motivated to employ any equivalent gas, such as Freon, as taught by Tickner in microbubbles to obtain useful contrast agents. Additionally, Ryan '545 teaches that such liposomes may encapsulate perfluorohydrocarbons, which would broadly encompass Freons as disclosed by Tickner. All of the cited art relates to contrast agents comprising gas-filled microparticles. One of ordinary skill in the art would have recognized that various equivalent gases, such as, Freon as taught by Tickner could be

used in gas-filled microparticulate contrast agents with a reasonable expectation of success, given Unger, Ryan '540 and '545 teach that a variety of gases (some of which overlap with those taught by Tickner) may be employed.

Claim 1 is rejected under 35 U.S.C. 103(a) as being obvious over Lohrmann (US 5,716,597).

Lohrmann teaches compositions comprising fluorinated gases with surfactants (columns 3 – 4 and examples 4, 7, and 10), their preparation, and their use in ultrasonic imaging.

While Lohrmann fails to teach all possible fluorinated gases, it would have been obvious to one of ordinary skill in the art that a variety of fluorinated gases could be used because Lohrmann teaches a large number of specific and diverse fluorinated species under the heading "gas-forming chemical," including a variety of fluorinated hydrocarbons (ex. perfluoropentane, decafluorobutane, etc.), halogenated hydrocarbons (2-bromo-1,1,1-trifluoroethane, fluorotrichloromethane, etc.), fluorinated amines, and sulfur hexafluoride in Table 1. Lohrmann even refers to the fluorinated species generically as the "fluorinated gas-forming compound" (column 4, line 52). One would have been motivated to substitute any gas which meets the criteria of being poorly soluble and would have been motivated to select from halogenated hydrocarbon or other fluorinated gases because a diverse list of fluorinated species (or "fluorinated gas-forming compounds") was shown to be suitable by Lohrmann.

Claim 1 is rejected under 35 U.S.C. 103(a) as being obvious over Klaveness (US 5,558,856), Unger (US 5,776,429), Unger (5,585,112), Quay (5,558,094), or Quay (5,393,524).

Klaveness, Unger '429, Unger '112, Quay '094, or Quay '524 each teach suspensions of microbubbles which contain various surfactants including lipids and further teach a number of fluorinated gases. Klaveness teaches the combination of a lipid (i.e. surfactant) with a polysaccharide as well as a fluorine containing gas (examples 19-22). Unger '429 and Unger '112 teach surfactant stabilized microspheres which contain a fluorinated gas (examples 1,6, and 7 or examples 1, 3, 4, 5, and 10, respectively). Quay ('524, column 7, lines 59 – column 8 line 50; Table II) or Quay ('094, example 1, column 16, lines 53 – column 17, line 7) teaches microbubbles stabilized with other materials than lipids, as well as generally teaching a variety of shell material. Quay and Quay teach several fluorinated gases as well as a specific example containing a fluorinated gas and a surfactant.

Since Klaveness, Unger '429, Unger '112, Quay '094, and Quay '524 are all drawn to using microbubbles containing a (fluorinated) gas for ultrasonic imaging, all are considered to be within the same field of endeavor.

While Klaveness, Unger '429, Unger '112, Quay '094, or Quay '524 fail to teach all possible combinations of any surfactant with any fluorinated gas, it would have been obvious to one of ordinary skill in the art that essentially any such combination could be made since the cited prior art broadly teaches the combination of various surfactants with fluorinated gases, as well as providing specific examples thereof. One of ordinary

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skill in the art would have been motivated to substitute essentially any known surfactant with a fluorinated gas to produce the most stable microbubble for ultrasonic imaging.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claim is properly rejected under 35 U.S.C. § 103.

Conclusion

No claims are allowed at this time.

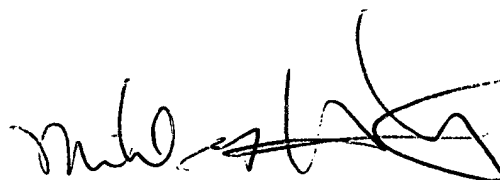
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lhs

A handwritten signature in black ink, appearing to read 'Michael G. Hartley', with a stylized flourish at the end.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER